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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,283

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Bal Ram Singh

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26161 7590 06/12/2007  
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EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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06/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/766,283

Applicant(s)

SINGH ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,7,17-26,30 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) 1,7,17-21,25,26 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24 and 33-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 7, 17-26, 30 and 33-37 are pending.

Applicants' amendment filed February 22, 2007 is acknowledged. Applicants' response has been fully considered. Claim 22 has been amended, and new claims 33-37 have been added. Claims 1, 7, 17-21, 25, 26 and 30 are non-elected inventions and are withdrawn from consideration. Therefore, claims 22-24 and 33-37 are examined.

### **Withdrawn Claim Rejections - 35 USC § 112**

2. The previous rejection of claims 22-24 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicant's amendment to the claims, and applicants' response at page 6 in the amendment filed February 22, 2007.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Previous rejection of claims 22-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained, and new claims 33-37 have been added.
4. Claims 22-24 and 33-37 are indefinite as to what result a therapeutically effective amount of the polypeptide complex would produce in the treatment, and what diseases are treated in the claimed method. Claims 23-24 and 33-37 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Response to Arguments

Applicants indicates since the specification states that “The dosage is adjusted, either in quantity or frequency, to achieve sufficient reduction in acetylcholine release to afford relief from the symptoms of the disease or condition being treated.” at page 13, lines 13 to 15, skilled practitioners would appreciate that the result of treatment would be a reduction in the symptoms of the disease being treated. Furthermore, the claims have been amended to “exaggerated release of acetylcholine”, and the specification discloses “An exaggerated release of acetylcholine would be any level of release that exceeds the normal parameters and causes aberrant physiological function. The diseases or conditions associated with an exaggerated release of acetylcholine can involve spasms of either smooth or skeletal muscle cells. More specifically, these diseases or conditions include spasmodic torticollis, essential tremor, spasmodic dysphonia, charley horse, strabismus, blepharospasm, oromandibular dystonia, spasms of the sphincters of the cardiovascular, gastrointestinal, or urinary systems, and tardive dyskinesia, which may result from treatment with an anti-psychotic drug such as THORAZINE® or HALDOL® at page 12, lines 6-17.” Thus, the metes and bounds of the claims are completely clear, and the rejection should be withdrawn (pages 7-8 of the response).

Applicants’ response has been fully considered. Regarding the term “excessive release of acetylcholine”, since independent claim (i.e., claim 22) has been amended to recite “exaggerated release of acetylcholine”, which has been described in the specification, thus the definition of the term is clear. However, regarding the outcome of the treatment, although the specification indicates the dosage is adjusted to sufficiently reduce acetylcholine release to afford relief from the symptoms of the disease or condition being treated, this limitation is not cited in the claimed

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methods, thus it is not clear what outcome an effective amount of the composition would bring.

Regarding the diseases associated with excessive release of acetylcholine, while the specification indicates the disease can involve spasms of either smooth or skeletal muscle cells, and include a list of diseases cited at page 12, lines 6-17, the limitation is not cited in the claim, thus it is not clear what are the metes and bounds for the diseases being treated. Therefore, the rejection is maintained.

5. Claims 23-24 recite the limitation "the excessive acetylcholine release" in line 1. There is insufficient antecedent basis for this limitation in the claim.

#### *Conclusion*

6. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
**PRIMARY EXAMINER**

CMK

May 31, 2006